## <u>REMARKS</u>

## A. Status of Claims

Claims 5, 7-10, 12-45, 46-59, and 60-73 were previously cancelled without prejudice.

Claims 1-4, 6, 11, and 74-90 are pending, with claims 1-2, 4, 11, 81, 83, 85, 87, 89 and 90 withdrawn from the consideration.

It is respectfully submitted that claims 3, 6, 74-80, 82, 84, 86, and 88 are encompassed by the elected invention.

## B. Claim Rejections- 35 U.S.C. § 102

Claims 3, 6, 74-80, 82, 84, 86-88, and 90 have been rejected under 35 U.S.C. §102(b) over the U.S. Patent No. 4,260,517 to Woodford ("The Woodford patent").

The rejection is respectfully traversed.

Independent claims 3, 6, 80 and 84 are all directed in part "to imparting a scent or scent profile" to a pharmaceutical dosage form during manufacture of the dosage form.

The Woodford patent is purportedly directed to finding "alternative sources for the aroma of certain controlled substances [i.e., cocaine]." *Column 1, lines 36-37*. "A unique feature of the ... invention [described in the Woodford patent is that] the actual aroma of cocaine is provided without the use of any cocaine or cocaine related materials." *Column 1, lines 62-64 (emphasis added)*.

The Woodford patent cannot therefore teach a step of "imparting a scent or scent profile to a pharmaceutical dosage form" as recited in independent claims 3, 6, 80 and 84, because it does not describe a pharmaceutical dosage form. In fact, it clearly states that "the actual aroma of cocaine is provided without the use of any cocaine or cocaine related materials." Column 1,

lines 62-64 (emphasis added).

With further regard to independent claims 3, 6, and 84, it is respectfully submitted that the Woodford patent does not teach "associating the scent or scent profile with the identity or source of the pharmaceutical dosage form" as recited in these claims.

With further regard to independent claim 80, it is respectfully submitted that the Woodford patent does not teach a scent or scent profile "in an amount or concentration which (i) is **below the human olfactory threshold of the scent or scent profile**" as recited in claim 80, because the Woodford patent describes, e.g., volatilization and subsequent dilution of the aroma (i.e., methyl benzoate) "to render the aroma **detectable by the human nose**." See, e.g., column 3, lines 9-14 (emphasis added); see also column 5, lines 15-24 ("... [w]hen the microparticles are broken the aromatics would be permitted to volatilize and mix with and be diluted by the surrounding air before they reach the nose for detection of the aroma").

In response to the Examiner's statement that the Woodford patent "discloses a method of identifying various forms of cocaine by imparting a scent to cocaine," Applicants respectfully note that the "imparting step" is not disclosed in the Woodford patent. In fact, the Woodford patent clearly states that "the actual aroma of cocaine is provided without the use of any cocaine or cocaine related materials." *Column 1, lines 62-64 (emphasis added)*.

In response to the Examiner's statement that "[s]cents are used to determine the source (region, soil condition) of the cocoa leaves used to make cocaine, as well as the purity of the processed cocaine (col. 1, lin. 44-54; col. 2, lin. 29-50)," the Examiner's attention is respectfully directed to these passages, which recite:

Generally speaking, the present invention relates to a method of providing the aroma of cocaine to the olfactory senses. More particularly, the present invention relates to a method of providing the aroma of various grades of "street cocaine" utilizing readily available, non-controlled substances. Specifically, methyl benzoate is the chemical substance which is responsible for the aroma of pure cocaine. Furthermore, a mixture of methyl benzoate, methyl cinnamate and the dimethyl ester of truxillic acid is responsible for the aroma of various other grades of cocaine...

The present invention relates to a method of providing the aroma of cocaine in its various grades and to a method of formulating those aromas.

Cocaine is generally encountered in a variety of different grades or purities. Pharmaceutical grade cocaine is usually the purest form available having a purity generally better than 99%. However, since cocaine is also often encountered from a variety of non-pharmaceutical sources, the cocaine often has a number of associate aromatics in combination with it. Such cocaine is sometimes referred to as "street cocaine." Furthermore, "street cocaine" may originate from a variety of different geographic areas. Soil conditions, temperature and rainfall in the growing area each affect different qualities of the aroma of the "street cocaine." These factors contribute to producing a different aroma between "street cocaine" and pharmaceutical grade cocaine and, also, between "street cocaines" having different geographical origins.

These passages do <u>not</u> describe the use of a scent to determine the source and purity of the processed cocaine, and therefore, respectfully, the Examiner's contentions are incorrect.

In response to the Examiner's statement that "[t]he scent is differentiated by a gas chromatography machine or mass spectrometer (col. 4, lin. 32-42)," Applicants respectfully note that the cited passage recites:

To produce the aroma of "street cocaine" this mixture is volatilized and then diluted with a gaseous non-odor masking diluent. Again, this may be accomplished by volatilizing the mixture of aromatics and diluting the volatilized aromatics with a gaseous non-odor masking diluent, such as air, in order to achieve a concentration of the mixture of aromatics detectable by the olfactory sense. Alternately, the mixture may be diluted with a carrier gas, such as nitrogen or helium, for use in analytical instruments such as gas chromatographs and/or mass spectrometers.

Contrary to the Examiner's assertion, this passage does <u>not</u> state that the "the scent is differentiated."

In response to the Examiner's statement that "[t]he invention can be applied during the manufacture of the cocaine and would react with cocaine to provide information regarding its origin," Applicants respectfully note that the <u>manufacture</u> of cocaine is not described in the Woodford patent. As stated above, the actual aroma of cocaine in the Woodford patent "is

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provided without the use of any cocaine or cocaine related materials." Column 1, lines 62-64 (emphasis added).

In response to the Examiner's statement that "[a]lso envisioned by the invention are methods of identifying cosmetics by imparting microencapsulated scents (col. 2, lin. 5-8)," Applicants respectfully note that the cited passage recites "[d]ue to the highly volatile nature of the associate aromatics of cocaine and cocaine related materials, the present invention is also useful for **producing** fragrances for perfume and cosmetics" (emphasis added). Contrary to the Examiner's assertion, this passage does not teach "methods of **identifying** cosmetics."

In response to the Examiner's statement that "[t]he microparticles are applied to the cosmetic so when they are broken they release the source identifying scent (col. 5, lin. 5-15)," Applicants respectfully note that the cited passage recites:

After the microcapsules have been formed, they are often adhered to a substrate to form a convenient strip. These microcapsule strips have been used previously to provide samples of perfumes and other fragrant substances. **The fragrance is released** by scratching the microcapsule strip with the fingernail or some other similar object. The scratching breaks some of the microcapsules and releases the contents of the capsules (emphasis added).

Contrary to the Examiner's assertion, this passage does not teach that "the **source** identifying scent" is released.

Independent claims 3, 6, 80 and 84 are therefore novel and non-obvious over the Woodford patent, because the Woodford patent does not teach or suggest each and every element of the present claims.

Claims 74-79, 82, 86-88 and 90 are novel and non-obvious over the Woodford patent by virtue of their dependency from independent claim 3, 6, 80 or 84.

Withdrawal of the rejection is respectfully requested.

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## **CONCLUSION**

An early and favorable action on the merits is earnestly requested. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

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